K 130990

MAY 0 9 2013

Special 510(k) Summary – Device Modification

Introduction

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 and the Safe Medical Device Act of 1990.

Submitter

Bio-Rad Laboratories, Inc.
Clinical Systems Division
4000 Alfred Nobel Drive
Hercules, CA 94545

Contact Person

Ebony McKinnies
Regulatory Affairs Representative

Date Submitted

April 5, 2013

Device Name

VARIANT™ II TURBO HbA1c Kit – 2.0, Catalog No.: 270-2455

Classification

Glycosylated hemoglobin assay, 21 CFR 864.7470 [LCP]

Predicate Device

Table 1: Predicate Device

Device Name	510(k) Number	Product Regulation and Code
VARIANT™ II TURBO HbA1c Kit – 2.0	K122472	21 CFR 864.7470 [LCP]

Intended and Indications for Use

The Bio-Rad VARIANT™ II TURBO HbA1c Kit – 2.0 is intended for the quantitative determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC) on the VARIANT II TURBO Hemoglobin Testing System. Measurement of hemoglobin A1c is effective in monitoring long term glycemic control in individuals with diabetes mellitus. The Bio-Rad VARIANT II TURBO HbA1c Kit – 2.0 is intended for professional Use.

Description of Change

The software updates include customer requested features, whereas both software and firmware include specific defect fixes. When compared to the predicate device, there are no changes to the performance specifications, intended or indications for use, or operating principles. Moreover, Risk Analysis and Verification/Validation testing results demonstrate that the changes do not affect product safety, effectiveness, and substantial equivalency claims.

Description of Instrument

The VARIANT II TURBO Hemoglobin Testing System is the next generation HPLC system with higher volume capability when compared to the VARIANT II testing system. The VARIANT II TURBO Hemoglobin Testing System provides an integrated method for sample preparation, separation, and determination of specific hemoglobin in whole blood. It is a fully automated, high-throughput system. It consists of 2 modules: the VARIANT II TURBO Sampling Station (VSS) and the VARIANT II TURBO Chromatographic Station (VCS).

A personal computer (PC) is used to control the VARIANT II TURBO System using Clinical Data Management (CDM™) software. The CDM software supports import of sample information from and export of patient results to a Laboratory Information System (LIS). Control results are displayed on Levy-Jennings Charts and are exportable to Unity Real Time™.

Table 2: FDA-cleared assays for use on the VARIANT II TURBO Hemoglobin Testing System with CDM Software

VARIANT II TURBO Assay	Assay Part No.	Component Names and Part Nos.	Explanation of Test
VARIANT II TURBO HbA1c Kit – 2.0	270-2455	The assay contains the following components – ▪ Whole Blood Primer, 270-0350, 270-0351, 270-0352 ▪ Elution Buffer A, 270-2456 ▪ Elution Buffer B, 270-2457 ▪ Calibrator/Diluent Set, 270-2458 ▪ CD-ROM, 270-2461 ▪ Analytical Cartridge, 270-2462 ▪ Sample Vials, 270-2149 Additional Required/Available components: ▪ Wash/Diluent Solution Set, 270-2730 ▪ Cartridge Holder Installation Kit, 270-2463 ▪ Prefilters, 270-2464 ▪ Stainless Steel Prefilter Adapters, 270-2465 ▪ Microvial Adapters, 270-2016-10, 270-2017-10	The VARIANT II TURBO HbA1c Kit – 2.0 is a well established method of measuring the level of Hemoglobin A1c in red blood cells. Therapy for diabetes requires the long-term maintenance of a blood glucose level as close as possible to normal levels to minimize the risk of long-term vascular consequences.

Comparison to Predicate Device

The following table shows the similarities and differences between the predicate and modified device.

Table 3: VARIANT II TURBO HbA1c Kit – 2.0

Feature	Predicate: Bio-Rad VARIANT™ II TURBO HbA_{1c} Kit -2.0, 510(k) 122472	Modified device: Bio-Rad VARIANT™ II TURBO HbA_{1c} Kit -2.0	
Similarities			
Technology	Ion-exchange high performance liquid chromatography		
Sample type	Anticoagulated whole blood (EDTA)		
Calibrator	Human anticoagulated whole blood treated with EDTA		
Calibration frequency	Once every 500 injections/ 2500 injections total column life		
Certification	Certified by the NGSP as traceable to the Diabetes Control and Complications Trial (DCCT) Reference method.		
Certification	Certified by the IFCC as traceable to the IFCC Reference Measurement Procedure.		
Instrument Control	Windows Operating System with Proprietary Assay Software		
Kit configuration	2500 Tests: Whole Blood Primer (2 each), Elution Buffer A (5 each), Elution B (1 each), Calibrator/Diluent Set (1 each), CD-ROM (1 each), Analytical Cartridge (1 each), Sample Vials – package of 100 (1 each).		
Chemistry	Cation Exchange Matrix		
Safety Standards for Electrical Equipment for IVD Use	BS EN 61010 Certified		
Electromagnetic Compatibility	BS EN 61326 Certified		
Reporting units	% HbA_{1c} (NGSP), mmol/mol HbA_{1c} (IFCC), or %HbA_{1c} (JDS)		
Intended Use	Intended for the quantitative determination of HbA_{1c} in human whole blood using ion-exchange HPLC on the VARIANT II TURBO Hemoglobin Testing System. Measurement of percent HbA_{1c} is effective in monitoring long-term glucose control in individuals with diabetes mellitus.		
Performance Claims	No change, claims transferred from predicate device.		
Differences			
CDM Software	CDM Software version 5.1.1	CDM Software version 5.2	
VARIANT II TURBO Testing System Firmware	EPROM VCS 41.507 VSS 51.505 VSS PUMP 4.50	EPROM VCS 41.508 VSS 51.523 VSS PUMP 4.50	FLASH VCS 42.507 VSS 52.523 VSS PUMP 5.00
Historical Database Review	N/A	Archive Viewer – this tool does not allow transmission to an LIS, and is not intended for repeat reporting.	

Risk Management Process for Device Modifications

In accordance with ISO 14971:2012, and internal risk management processes and procedures a defined risk analysis was used to identify, mitigate, or eliminate potential risks associated with the device modifications. For each identified risk, a Failure Mode and Effects Analysis (FMEA) was conducted. This was performed in a systematic manner by a trained risk assessment team until consensus was reached that an adequate analysis had been performed.

The risk evaluation for the device software and firmware modifications included the following tasks:

- Reviewed modifications and design inputs to identify potential risks and hazards;
- Reviewed existing product risk tables and customer complaints to identify potential risks and hazards;
- Considered requirements of IEC 62304:2009, Software Design and Development processes and plan to identify potential risks and hazards;
- Identified and implemented risk mitigations and hazard controls through software, hardware, and labeling for misuse and use scenarios;
- Updated existing FMEA and Hazard Analysis tables with newly identified risks, software defects, residual risks, mitigations and hazard controls;
- Evaluated modified product using established verification and validation processes, plans and protocols with appropriate acceptance criteria that determined whether risk mitigations, hazard controls, and residual risks were as safe and effective as the predicate device;
- Conducted a comprehensive risk management review and wrote a Risk Management Report that summarized all risk activities and deemed the modified product safe, effective, and comparable to the predicate device.

Design verification/validation tests met established acceptance criteria.

Conclusion

When considering the similarities of the intended use, general features and characteristics of the assay, and use of the same technology, it can be concluded that the VARIANT II TURBO HbA1c Kit – 2.0 is substantially equivalent to the cleared and currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 9, 2013

Bio-Rad Laboratories, Inc.
C/O Ms. Ebony McKinnies
4000 Alfred Nobel Drive
HERCULES CA 94547-1803

Re: K130990
Trade/Device Name: VARIANT™ II TURBO HbA1c Kit - 2.0
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: II
Product Code: LCP
Dated: April 05, 2013
Received: April 10, 2013

Dear Ms. McKinnies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol F. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k130990

Device Name: VARIANT™ II TURBO HbA1c Kit – 2.0

Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiologic Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k130990